

Please amend the application filed on even date herewith prior to proceeding with its examination.

IN THE CLAIMS

1. (Currently Amended) Self-supporting films comprising:
 - a) a filmogenic substance consisting of a maltodextrin,
 - b) a plasticiser,
 - c) an active ingredient for food or pharmaceutical use,

5 wherein characterised in that said films are free from of hydrocolloids.
2. (Currently Amended) Self-supporting films as claimed in claim 1,
wherein characterised in that the maltodextrin (a) has a dextrose content of less than[t] 50 expressed in equivalents.
3. (Original) Self-supporting films as claimed in claim 2 wherein said
10 dextrose content is between 11 and 40.
4. (Currently Amended) Self-supporting films as claimed ~~in any one of in~~ claims 1-3, wherein characterised in that the plasticiser is [chosen] selected from the [class] group consisting of polyalcohols, citric acid esters, sebacic acid esters or their mixtures.
- 15 5. (Currently Amended) Self-supporting films as claimed in ~~any one of~~ claims 1[-4], wherein characterised in that the plasticiser is [chosen] selected from the [class] group consisting of propylene glycol, glycerine, sorbitol, maltitol and their relative mixtures.
6. (Currently Amended) Self-supporting films as claimed in ~~any one of~~
20 claims 1-5, wherein characterised in that the active principle for food use is an active principle with a breath freshening action and/or indicated for oral hygiene or an active principle suitable for nutritional supplementation.
7. (Currently Amended) Self-supporting films as claimed in claim 6,
wherein characterised in that said active principle for food use is [chosen] selected
25 from the group consisting of menthol and eugenol.

8. (Currently Amended) Self-supporting films as claimed in claim 6 wherein said active principle suitable for nutritional supplementation is [chosen] selected from the group consisting of mineral salts normally used for such purpose[,] and vitamins.
- 5 9. (Original) Self-supporting films as claimed in claim 8 wherein the vitamin is ascorbic acid.
- 10 10. (Currently Amended) Self-supporting films as claimed in ~~any one of~~ claims 1-5, wherein characterised in that said active principle for therapeutic use is [chosen] selected from the group consisting of active principles with essentially topical activity.
11. (Currently Amended) Self-supporting films as claimed in claim 10, wherein characterised in that said active principle is [chosen] selected from the [class] group consisting of antibacterial, antimycotic, antiviral agents and disinfectants of the oral cavity.
- 15 12. (Currently Amended) Self-supporting films as claimed in ~~any one of~~ claims 1-5 wherein the active principle for therapeutic use is [chosen] selected from the [class] group consisting of active principles with essentially systemic activity.
- 20 13. (Currently Amended) Self-supporting films as claimed in claim 12, wherein characterised in that said active principle with essentially systemic activity is [chosen] selected from the [class] group consisting of anti-inflammatory, analgesic, antipsychotic, hypnotic, anxiolytic, antihypertensive, myorelaxant, antimigraine, antiparkinsonian, antiemetic, antihistaminic, beta blocking and antiasthmatic agents.
- 25 14. (Currently Amended) Self-supporting films as claimed in ~~either of~~ claims 12 ~~or 13~~, wherein characterised in that said principle is [chosen] selected from the [class] group consisting of: Piroxicam, Ketoprofen, Sodium diclofenac, Tramadol hydrochloride, Morphine, Nifedipine, Diazepam, Lorazepam, Alprazolam, Bromazepam, Triazolam, Lormetazepam, Zolpidem, Paracetamol,
- 30 Selegiline, Atenolol, Salbutamol, Sumatriptan, Clozapine, Cetirizine, Ondansetron, Fentanyl and their pharmaceutically acceptable salts.

15. (Currently Amended) Self-supporting films as claimed in ~~any one of~~ claims 1-14 14, characterised by containing maltodextrin at concentrations between 40 and 80% by weight, plasticiser in concentrations between 15 and 55% by weight and the active principle for food or pharmaceutical use in a quantity
5 between 0.05% and 30% by weight on the total weight of said film.
16. (Currently Amended) Self-supporting films as claimed in ~~any one of~~ claims 1-15, characterised by containing other excipients [chosen] selected from the [class] group consisting of anticaking agents, sweeteners, flavourings, colouring agents, preservatives, acidity regulating systems and mixtures thereof.
- 10 17. (Currently Amended) Self-supporting films as claimed in claim 16, wherein ~~characterised in that~~ said antisticking agents are [chosen] selected from the [class] group consisting of microcrystalline cellulose, colloidal silica and talc.
18. (Currently Amended) Process for preparing self-supporting films claimed in ~~any one of~~ claims 1-17, comprising the following steps:
- 15 i) mixing the maltodextrin, plasticiser and active principle for food or therapeutic use ~~are mixed~~,
- ii) extruding the mixture coming ~~derived~~ from the preceding step ~~is extruded in an extruder~~.
19. (Currently Amended) Process as claimed in claim 18, [characterised in
20 that] wherein the extrusion step (ii) is preferably conducted at a temperature between 60 and 120°C.
20. (Currently Amended) Process as claimed in ~~either of~~ claims 18 and 19, ~~characterised by being~~ conducted in a single screw extruder.
21. (Currently Amended) Process for preparing self-supporting films
25 claimed in ~~any one of~~ claims 1-17, characterised by comprising the following steps:
- i) dispersing the maltodextrin, plasticiser and the active principle for therapeutic or food use ~~are dispersed~~ in a polar solvent at a temperature between 60 and 105°C,
- ii) rolling the mixture obtained in the preceding step ~~is rolled onto a~~ silicone paper
30 and drying it and then dried,
- iii) removing the silicone paper ~~is removed~~ from the film obtained in the preceding step.

22. (Currently Amended) ~~The~~ Process as claimed in claim 21, wherein
~~characterised in that~~ the polar solvent used in step (i) is preferably [chosen]
selected from the [class] group consisting of water, a water miscible solvent and
relative mixtures thereof.

5 23. (Currently Amended) Process as claimed in claim 22, wherein
~~characterised in that~~ said solvent consists of water and or a water-ethanol mixture.

24. (Currently Amended) Process as claimed in claim 23, wherein
~~characterised in that~~ the temperature of steps (i) and (ii) is between 60 and 105°C.

25. (Currently Amended) Process for preparing self-supporting films
10 ~~claimed in any one of claims 1-17, comprising the following steps:~~
i) mixing the maltodextrin, plasticiser and active ingredient for food or therapeutic
use ~~are mixed,~~
ii) granulating ~~the mixture was granulated,~~ and sieving the mixture ~~ed~~ and mixing
~~ed it~~ with an anti sticking agent,
15 iii) storing the granules ~~were stored~~ at least for 12 h,
iv) extruding the granules coming ~~derived~~ from the preceding step ~~were extruded~~
~~in an extruder for~~ thereby obtaining the edible film.

26. (Currently Amended) Process as claimed in claim 25, wherein
~~characterised in that~~ the extrusion step (ii) is preferably conducted at a
20 temperature between 70 and 140°C.

27. (Cancelled)